UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	MDL No. 2419 Dkt. No 1:13-md-2419 (RWZ)
THIS DOCUMENT RELATES TO:	)	
Simas v. Abdul R. Barakat, M.D., and Ocean State Pain Management, P.C. 1:13-cv-10943-RWZ	)	

REPLY OF THE DEFENDANTS, ABDUL R. BARAKAT, M.D., AND OCEAN STATE PAIN MANAGEMENT, P.C., TO PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO DISMISS PRODUCT LIABILITY AND CONSUMER PROTECTION CLAIMS OF THE PLAINTIFFS

The Defendants, Abdul Barakat, M.D., and Ocean State Pain Management, P.C., file this Reply pursuant to Local Rule 7.1(b)(3) to Plaintiffs' Opposition to Defendants' Motion to Dismiss Product Liability and Consumer Protection Claims ("Plaintiffs' Opposition") in order to address certain misinterpretations of law contained therein. The Defendants, Abdul Barakat, M.D., and Ocean State Pain Management, P.C. (hereinafter, collectively "the Defendants"), by undersigned counsel, respectfully move this Honorable court to dismiss the Plaintiffs' claims of product liability and violations of Massachusetts and Rhode Island consumer protection statutes pursuant to Fed. R. Civ. P. 12(b)(6), Local Rule 7.1, and appropriate Massachusetts law.

I. INTRODUCTION

The Defendants filed the underlying Motion to Dismiss the above-referenced claims, as well as a Memorandum in Support, on November 6, 2015. See Dkt. No 2390. Plaintiffs filed

their Opposition and Affidavit in Support (hereinafter "Opposition") on January 15, 2016. See Dkt. 2591; Dkt. 2592. The Defendants summarize their position for context below and now respond directly to the unsupported arguments made by the Plaintiffs in their Opposition. A more detailed analysis of the case law is outlined in the Defendants Motion to Dismiss and Memorandum in Support, adopted herein. See Dkt. 2390.

In their Opposition, Plaintiffs seem to believe that just because they make an assertion in their Complaint those claims are unassailable and sufficient to survive a motion to dismiss. See Dkt. 2591 at p. 3-4, 6. On the contrary, a pleading that merely offers "labels and conclusions" or a "formulaic recitation of the elements of a cause of action" is *insufficient*. Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007) [emphasis added]. The Court need not accept as true a plaintiff's bald assertions or legal conclusions couched as facts. Id. Even if accepted as true, it must also be "plausible on its face." Id. at 570. Dismissal is appropriate if a plaintiff's supposed well-pleaded facts do not "possess enough heft to show that plaintiff is entitled to relief." Ruiz Rivera v. Pfizer Pharmaceuticals, LLC, 521 F.3d 76, 84 (1st Cir. 2008).

The above is certainly true concerning the claims at issue in these pleadings. Consideration of the question of whether the Plaintiffs' product liability claims are sufficiently well-pleaded does not require postponement to the opening of case-specific discovery in June 2016 or later, as suggested by the Plaintiffs. See Dkt. 2591 at p. 15. The applicable standard at issue, namely whether the provision of medical services predominated any alleged sale of goods, is the same in Massachusetts as it is in the other jurisdictions where the court has already ruled in favor of the defendants with respect to this issue. The Defendants request that the Court again apply the same "essence of the transaction" test and allow the Defendants' motion.

II. RESPONSE ARGUMENT

A. The Plaintiffs' reliance on the ruling of Phillips v. Medtronic is not persuasive given this Court's consistent rulings that the administration of MPA by defendant pain clinics involves the provision of a service with goods only incidentally involved.

Massachusetts law clearly precludes the Plaintiffs' product liability claims against the Defendants. As laid out in the Defendants' original Memorandum of Law, see Dkt. 2390 at p. 4, and as agreed-to in the Plaintiffs' Opposition, see Dkt. 2591 at p. 4-5, claims for breaches of the implied warranties of merchantability and/or fitness for a particular purpose under M.G.L. c. 106, §§2-314 and 2-315, or of an express warranty under § 2-313, must arise out of "transactions in goods" and not the provision of services. Phillips v. Medtronic, Inc., 754 F.Supp.2d 211, 216 (2010) (citing Mass. Gen. Laws c. 106, § 2-201). The breach of warranty theories are not available where "the predominant factor, thrust, or purpose" of the transaction is the "rendition of service, with goods incidentally involved."[1] Phillips, 754 F.Supp.2d at 216; Mattoon v. City of Pittsfield, 56 Mass.App.Ct. 124, 141 (2002) (quoting Bonebrake v. Cox, 499 F.2d 951, 960 (8th Cir. 1974)). The Plaintiffs further admit that the Phillips court recognized that, under Massachusetts breach of warranty provisions, a claim can only be brought against a "seller" of goods. Dkt. 2591 at 5; Phillips, 754 F.Supp. at 216. The Plaintiffs correctly note that the Supreme Judicial Court of Massachusetts resolved all ambiguities in the law in favor of the plaintiffs and inferred that the Massachusetts state courts would permit the Phillips' product liability claims to survive. Dkt. 2591 at 5; Phillips, 754 F.Supp. at 217.

The ultimate holding of Phillips is not contested by the Defendants, yet the Plaintiffs appear to believe that the holding alone should carry the day. The Defendants' argument does not depend on the individual facts of Phillips, but in their Memorandum of Law the Defendants

[1] The evidence will demonstrate that the Defendants are not "sellers" of goods, but, in a light most favorable to the Plaintiffs for purposes of this argument, the Defendants will assume that they are "sellers."

still distinguished the facts in the event that the Court undertakes a fact-specific analysis. The Defendants have conceded that the Phillips court opted to permit those plaintiffs' warranty claims to survive, albeit while giving the plaintiffs the extreme benefit of the doubt.

For the purposes of the Defendants' instant Motion to Dismiss, the Defendants suggest that the Court only need consider the following: (1) the warranty standards defined in Mattoon and referenced in Phillips, and (2) this Court's prior rulings that the provision of MPA by pain clinics was clearly a rendition of service with goods only incidentally involved. In effect, this Court has already ruled on multiple occasions that the Plaintiffs' product liability claims must necessarily fail under its application of the same language found in Phillips and Mattoon. See MDL Case No. 1:13-md-2419 (RWZ), Dkt. No. 2225 at p. 5, Dkt. No. 1642 at p. 10, and Dkt. No. 2700 at p. 4-5. In prior rulings, this Court dismissed strict liability claims by repeatedly holding that the predominant factor, thrust, or purpose of epidural steroid injections is the rendition of service, with goods incidentally involved. See id.; see also Phillips, 754 F.Supp.2d at 216; Mattoon, 56 Mass.App.Ct. at 141. With regard to the warranty claims asserted by the Plaintiffs here, Massachusetts courts apply the same "predominant purpose" or "essence of the transaction" language, reproduced above and described in full in both the Defendants' Memorandum of Law and the Plaintiffs' Opposition. See Phillips, 754 F.Supp.2d at 216; Mattoon, 56 Mass.App.Ct. at 141; Dkt. 2390 at p. 4; Dkt. 2591 at p. 4-5.

When analyzing the applicability of MDL plaintiffs' strict liability claims under Illinois law, applying the same type of predominant purpose test described in Phillips and Mattoon, this Court held, "There is no question here that plaintiffs were billed, separately, for both a service (the act of injection), and a product (the MPA). However, the provision of the MPA was part-and-parcel with the service of its injection – the only purpose of the visit was the injection itself,

something only a physician with special skill could provide. Under Illinois law, there is no action for strict liability on the complaint as alleged." See Dkt. No. 1642 at p. 10.

While engaging in the same analysis under Maryland law, this court again held that services predominated over the sale of goods and referred directly to its own prior holding, namely that the provision of MPA was part-and-parcel with the service of its injection. See Dkt. No. 2225 at p. 5. This Court further supported its consistent reasoning by referencing Maryland law. Phipps v. Gen. Motors Corp., 278 Md. 337, 344 (1976); Burton v. Artery Co., 279 Md. 94, 109 (1977) ("whether [the contract's] predominant factor, [its] thrust, [its] purpose, reasonably stated, is the rendition of service, with goods incidentally involved (e.g., contract with artist for painting) or is a transaction of sale, with labor incidentally involved (e.g., installation of a water heater in a bathroom)" determines the applicability of strict liability).

The Court recently issued its Opinion and Order on the respective motions for summary judgment offered by the Plaintiffs' Steering Committee and the Tennessee Defendants pertaining to product liability claims. See Dkt. 2700. The parties' motions related to whether the Tennessee Health Care Liability Act ("THCLA") or the Tennessee Products Liability Act ("TPLA") apply to the Tennessee cases. See Dkt. 2300; Dkt. 2462. The Court ruled that both statutes could apply given that the plaintiffs' allegations concern both a defective product and the provision of health care services, however, the THCLA takes precedence as the more specific statute in lieu of the more general one. Dkt. 2700 at p. 5. Significant to the analysis here, the Court stated that "Plaintiffs' allegations concern the injection of contaminated MPA *as a part of pain-treatment services performed by medical professionals, and therefore plainly relate to the provision of health care services*." Id. at p. 5, FN 3 [emphasis added]. The Court also stated that "the plaintiffs have asserted a cause of action concerning a product - MPA - that adversely

affected them *as the result of receiving health care services - MPA injections*. Id. at p. 4 [emphasis added]." There is no such statutory tension in Massachusetts, however, the Defendants request that the Court continue to employ consistent language that MPA was only administered as part of the provision of healthcare services.

The above cases illustrate this Court's stance that the provision of MPA was part-and-parcel with the service of its injection. See Dkt. 1642; Dkt. 2225; Dkt. 2700. Assuming *arguendo* that medical devices can be equated to injectable corticosteroids in this scenario, and that the Phillips court left open the question of whether a hospital could be deemed a seller of medical devices in the context of product liability claims, this Court has already closed the door on that question with respect to MPA. See id. The Plaintiffs' claims arise out of warranty rather than strict liability, but Massachusetts applies the same legal standards analyzed by this Court in the cases described above. See Phillips, 754 F.Supp.2d at 216; Mattoon, 56 Mass.App.Ct. at 141. The breach of warranty claims must arise out of "transactions in goods" and not the provision of services, Mass. Gen. Laws c. 106, § 2-102, and the theory is not available in the case of a service, with goods only incidentally involved. Mattoon, 56 Mass.App.Ct. at 125. The Court can choose to stop the analysis there and apply another consistent holding that, with respect to the provision of MPA by pain clinic defendants like Dr. Barakat and Ocean State, services predominated any alleged sale of goods and the breach of warranty claims must fail as a result. The Plaintiffs have failed to offer any additional facts which would warrant a reversal in this Court's continued application of this standard.

B. The Plaintiffs misinterpret the Defendants' argument concerning other favorable MDL decisions.

As stated repeatedly in the Defendants' Memorandum of Law, there is no disagreement

over the fact that there is no strict liability cause of action in Massachusetts. In their opposition, the Plaintiffs spend several pages explaining how other decisions in the MDL have been based on strict liability law, however, this misses the Defendants' point entirely. See Dkt. 2591 at p. 8-10. The Defendants contend that the standards relied upon by the Court in consideration of other product liability motions and the language then used in the Court's written opinions, see Dkts. 2225 and 1642, match the standards set out in Phillips and Mattoon. See 754 F.Supp.2d at 216; 56 Mass.App.Ct. at 125. Therefore, the Defendants suggest that the same result should follow under Massachusetts own standards – that the provision of MPA was predominantly a healthcare service and the Plaintiffs' warranty claims necessarily fail as a result. See id.

The Plaintiffs reference the court's ruling from August 29, 2014 concerning the aforementioned argument between the Plaintiffs' Steering Committee and the Tennessee Defendants over the THCLA and TLPA. See Dkt. 2591 at p. 9. However, the Court has now ruled that the THCLA controls and summary judgment has been entered in the Tennessee Defendants' favor. See Dkt. 2700 at p. 5. The THCLA precluded faultless liability and there is no equivalent to the strict liability of the TLPA in Massachusetts, as agreed-to by the Plaintiffs. Id. at p. 4-5; Dkt. 2591 at p. 8-10. The Defendant referenced the Court's written opinion in the preceding section to further highlight the Court's continued description of the provision of MPA as a healthcare service.

The Plaintiffs also reference the BKC Defendants' motion, pointing out that while the doctors were exempt from liability under the Ohio Product Liability Act ("OPLA"), the pain clinic was not. See Dkt. 2591 at p. 9. The doctors were not subject to strict liability because each was a "provider of professional services who, incidental to a professional transaction the essence of which is the furnishing of judgment, skill, or services, sells or uses a product." This

language again matches the language found in Phillips and Mattoon. See 754 F.Supp.2d at 216; 56 Mass.App.Ct. at 125. With respect to the pain clinic, the Court followed the Ohio statute's language of strict liability, which does not exist in Massachusetts, and cited to a case involving a hospital's duty to warn under the OPLA.

The Defendants have already explained there stance with respect to Dkt. 2225, which examined Maryland law pursuant to the Box Hill Defendants' products liability motion. The Plaintiffs urge the Court to continue to apply state law to determine the appropriate outcome of product liability claims, which is entirely proper. The Defendants merely contend that the Court has already settled the "predominant purpose" test in favor of the provision of MPA being a healthcare service, and that it should continue to adhere to this finding when it reviews and applies the standards laid out in Mattoon and referenced in Phillips. See 56 Mass.App.Ct. at 125; 754 F.Supp.2d at 216.

C. If the Court deems it necessary to compare the facts of Phillips to the facts of the instant case, the Phillips decision is still distinguishable.

If a comparative analysis to Phillips is ultimately required by the Court, the Defendants contend that the instant fact pattern is still clearly distinguishable. The Phillips court noted that its holding only applied to "medical devices" based on a small handful of state court cases. See 754 F.Supp.2d at 217. A proper comparison of facts would have to be conducted under the rubric of the "essence of the transaction" test applied in both Phillips and Mattoon. See 754 F.Supp.2d at 216-217 (citing Mattoon, 56 Mass.App.Ct. at 124).

In their Opposition, the Plaintiffs draw a false dichotomy between the term "movable" and the concept of a permanent implant. See Dkt. 2591 at 6. The Plaintiffs cite to the proper statute but then ignore its language that, *at the time of contract for sale*, a pain pump is movable.

See M.G.L. ch. 106, sec. 2-105(1) [emphasis added]. The Plaintiffs next offer an unsupported argument by concluding, without any explanation whatsoever, "It requires much less skill and knowledge to provide an injection than it does to operate on someone to insert a medical device." See Dkt. No. 2591 at 6. The Plaintiffs misrepresent the true nature of an epidural steroid injection and liken it to something akin to an intramuscular shoulder injection or routine insulin injection. This could not be further from the truth.

As has been demonstrated in countless instances during common discovery in the MDL, an epidural steroid injection requires a much higher degree of training and expertise. It is not logically or physically possible, for both medical and anatomical reasons, for a patient to give himself an epidural steroid injection in the back. Mr. Simas depended on Dr. Barakat's specialized skill to inject just the right amount of drug into the exact location near the spine with a long needle using fluoroscopic (x-ray) guidance under negative pressure for maximum effectiveness and pain relief. Without Dr. Barakat's expertise, the drugs utilized in epidural steroid injections, MPA, Depo-Medrol, or otherwise, would have been useless on their own. Further supporting the skill required for this procedure are the risks of performing the procedure imprecisely, including paralysis or death. That is not something that the Plaintiff could have done without specialized expertise and training, which Dr. Barakat possessed. Patients do not take home vials of steroid solutions to use as they see fit like Tylenol or Advil from a convenience store, rather, they return to Ocean State for repeat injections performed at the facility. If the sale of a product occurred, it was non-divisible from the service provided, so the service predominates. See Mattoon, 56 Mass.App.Ct. at 140-142. It is clear that the performance of the service/procedure was non-divisible from whatever product was used and the

main object of the alleged hybrid contract was not to purchase corticosteroids, but to receive an invasive procedure for pain relief.

The Plaintiffs next attempt to distinguish the facts of Mattoon from the instant case by stating that "the water in Mattoon was not created or manufactured by the defendant-city." See Dkt. 2591 at 7. If anything, such an observation should bolster the Defendants' position. The Plaintiffs conveniently sidestep the glaring fact that the MPA at issue in this case was not created or manufactured by the Defendants, but rather by NECC. Id. The Plaintiffs distract the Court by pointing out that water is a natural substance while MPA was manufactured, again ignoring that the Defendants had nothing whatsoever to do with the creation of MPA. Id. The Plaintiffs deliberately avoid the fact that the city in Mattoon stored, treated, and distributed a product *it did not create itself* because it defeats the Plaintiffs' goal of distinguishing Mattoon from the instant case. Id.; see 56 Mass.App.Ct. at 140-142 [emphasis added]. The Defendants, following from the same language of Mattoon, stored and distributed MPA that it did not manufacture. Id. at 141. Thus, just like in Mattoon, the Defendants' provision of a service was the predominant factor in the transaction. Id. at 140-142. Consequently, the Defendants request the same dismissal of product liability claims as has been provided by this Court to other MDL defendants based on the same "essence of the transaction" or "predominant purpose" reasoning.

At the end of Section 2 of their Opposition, the Plaintiffs' include a brief paragraph that finally addresses the "essence of the transaction" test that they should have been addressing from the start. See Dkt. 2591 at 7. In an effort to persuade the court that service does not predominate, the Plaintiffs are only able to muster brief, conclusory opinions that MPA is of "paramount importance to the transaction," "[T]he injection itself is futile without the MPA," and "[T]he performance of the injection, therefore, is incidental to the provision of the particular

drug in question." Id. The Plaintiffs offer these three short opinions, provide no support whatsoever, and move on. See id. The Plaintiffs ignore the fact that the use of corticosteroids by pain clinics in epidural steroid injections does not rise and fall with the existence of MPA. See id. Epidural steroid injections are still being performed not only by Ocean State, but by health care entities across the country, and this practice has continued despite the complete non-existence of NECC and the MPA compounded at their facility. If the Court is to believe the Plaintiffs allegations that the Defendants should not have purchased from NECC, then that means that reasonable alternatives must have been available for purchase. Therefore, according to the Plaintiffs' own theory regarding the transaction between Mr. Simas and the Defendants, any number of medications could have been injected for the same desired effect, making the healthcare *service* far more important than the alleged *good*.

D. The Plaintiffs have failed to describe deceptive trade practices that would substantiate their Massachusetts and Rhode Island consumer protection claims.

The Plaintiffs properly direct the Court to the need for allegations concerning "any entrepreneurial or business aspect of [the] medical practice, to which 93A could apply, or whether they merely state a claim for the negligent delivery of medical care." See Dkt. 2591 at p. 12 (citing Darviris v. Petros, 442 Mass. 274, 280 (2004). The Plaintiffs state that the underlying nature of the claim is that the defendants purchased, sold, and administered MPA to Mr. Simas without patient-specific prescriptions in violation of state law, but fail to provide the state law applicable to pain clinics in 2012. See Dkt. 2591 at p. 12-13. Similarly, the Plaintiffs contend that the Defendants needed to be aware that NECC and NECC-related drugs were not FDA-approved but fail to provide the applicable law. See id. at p. 12.

The Plaintiffs continue to offer insufficient descriptions of "deceptive" acts or practices

engaged in by the Defendants. See id. The Complaint merely makes blanket assertions that the Defendants "actively, knowingly, and deceptively concealed the product's dangerous properties and life-threatening risks," "misrepresent[ed] the nature, quality, and characteristics about the products they sold," and "knowingly and falsely represent[ed] that the NECC Contaminated Drugs were fit to be used for the purpose for which they were intended, when, in fact, they were defective and dangerous." See Plaintiffs' Steering Committee's Second Amended Master Complaint, Civil Action No. 1:13-md-2419-RWZ, Dkt. No. 1719 at ¶¶ 251, 255, 256. The mere fact that medication was purchased from a seller does not, without more, equate to a deceptive act on the part of the Defendants. While NECC's acts and practices were obviously deceptive given the manner in which it marketed and sold its contaminated product, there is no evidence that the Defendants were aware of or participated in these deceptive practices. The Plaintiffs' Complaint merely offers "labels and conclusions" which should be held to be insufficient under Twombly, 550 U.S. at 555.

E. There is no personal connection to Massachusetts to justify a Massachusetts consumer protection claim.

The Defendants deny that they were engaged in "trade" with Mr. Simas, let alone deceptive or unfair trade practices. Assuming that to be true for purposes of this argument only, the Defendants are still not subject to violation of 93A. Chapter 93A only applies to "trade or commerce directly or indirectly affecting the people of [Massachusetts]." See M.G.L. Ch. 93A(1)(b). Dr. Barakat is a physician licensed to practice in Rhode Island. Ocean State Pain Management, P.C., is a Rhode Island corporation. The Defendants are alleged to have sold or distributed MPA in their possession in Rhode Island to Rhode Island patients in their facilities located in Rhode Island, said patients then suffering injury in Rhode Island. It is undisputed that

the Plaintiffs are residents of Rhode Island.

Further clarification can be found in Snyder v. ADS Aviation Maintenance, 2000 Mass.Super. LEXIS 5 at *20 (Jan. 10, 2000). Snyder maintains that jurisdiction under Ch. 93A, § 9, is determined by the Massachusetts long-arm statute. See id. More precisely, the only long-arm statute section that applies is Ch. 223A, § 3(d). See id. Section 3(d) provides, in pertinent part, that "[A] court may exercise personal jurisdiction over a person...as to a cause of action…arising from the person's…causing tortious injury in this commonwealth by an act…outside this commonwealth if he regularly…engages in…or derives substantial revenue from goods or services rendered in this commonwealth."

The Plaintiffs bear the burden of establishing sufficient facts upon which to predicate personal jurisdiction over the Defendants under the Commonwealth's long-arm statute. Tatro v. Manor Care, Inc., 416 Mass. 763, 767 (1994). The first distinct element under sec. 3(d) requires the plaintiffs to demonstrate that the defendant's act or omission caused a tortious injury inside Massachusetts. Cunningham v. Adrox, Inc., 40 Mass. App. Ct. 279, 281 (1996). Unlike in Snyder, where four individuals suffered injuries and died from a plane crash in Massachusetts, Plaintiffs in the instant case suffered a tortious injury in Rhode Island after contracting meningitis from medical care in Rhode Island. Having failed the first element, let along failing to meet their burden of proof, Plaintiff's Massachusetts consumer protection claims against the Defendants should be dismissed. As such, there is no need to consider the second prong of the test involving contacts and derivation of business in Massachusetts, although that element also favors the Defendants.

In the Court's order regarding Box Hill Defendants' 93A argument, this Court stated that NECC was a Massachusetts corporation and therefore a "person" under the meaning of the

statute. See Dkt. 2225 at p. 9. If NECC is the individual being used by the Court for jurisdiction purposes, then the Plaintiffs' argument is limited by the fact that NECC is no longer a party in this action. NECC is not even a corporation anymore since the entity has been dissolved. The question of whether or not something affects or does not affect NECC no longer has any bearing in the instant litigation. As such, there is no personal relationship to Massachusetts, and this should be another factor requiring dismissal of the Plaintiffs' Massachusetts Consumer Protection claims.

III. CONCLUSION

Based on the above arguments, as well as the Defendants' Motion to Dismiss and Memorandum of Law in Support of the same, the Defendants seek dismissal of the Plaintiffs' claims of (1) product liability and (2) violation of the Massachusetts and Rhode Island Consumer Protection statutes pursuant to F.R.C.P. 12(b)(6).

Respectfully submitted,
By their attorneys,

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Dated: 3-7-16

CERTIFICATE OF SERVICE

I hereby certify that on March 7, 2016, I served the above Motion upon the Clerk of the Court, using the CM/ECF system, which then sent a notification of such filing (NEF) to all counsel of record.

/s/ Thomas M. Dolan
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